

UNITED STATES BANKRUPTCY COURT DISTRICT OF NEW JERSEY	
Caption in Compliance with D.N.J. LBR 9004-2(c)	
<b>Larry K. Lesnik</b> <b>NORRIS McLAUGHLIN &amp; MARCUS, P.A.</b> <b>Attorneys for P&amp;L Development of New York</b> <b>and PLD Acquisitions, LLC</b> <b>721 Route 202/206, Suite 200</b> <b>P.O. Box 5933</b> <b>Bridgewater, NJ 08807-5933</b> <b>(908) 722-0700</b>	
In Re:	Chapter 11
ADVENT PHARMACEUTICALS, INC.,	Case No: 11-25437/KCF
Debtor.	Hearing Date October 3, 2011

**CERTIFICATION OF ROBERT J. ANDERSON, ESQ. TO CORRECT  
MISINFORMATION IN DEBTOR'S RESPONSE TO OPPOSITION  
TO PENDING MOTION TO SELL ASSETS**

Robert J. Anderson, of full age, hereby certifies and says:

1. I am Senior Director of Quality & Regulatory Affairs of PLD Acquisitions, LLC t/a Avema Pharma Solutions ("Avema"). I am familiar with the facts set forth herein through my personal knowledge.
2. I am making this certification to correct both factual and legal misinformation contained in pleadings filed by the above Debtor in response to objections filed by Avema and the Debtor's secured creditor UPS Capital Business Credit ("UPSCBC") to the Debtor's motion to sell assets.
3. In paragraph 4 of the Certification of Bharat Patel in reply to the aforesaid objections, Mr. Patel, who clearly would lack personal knowledge with respect to this issue, asserts that at "no time has PLD requested or attempted to obtain that

documentation by communication or legal action”, referencing documentation that he asserts is required in order to properly transfer ownership of an ANDA.

4. While I believe that this issue in and of itself is a red herring, as obtaining possession of documentation is not necessary to confirm the effectiveness or finality of a transfer of an ANDA by a secured creditor to a bonafide purchaser thereof, in point of fact, Avema did obtain all such documentation directly through the Food & Drug Administration (“FDA”). While the information may also be in the Debtor’s possession, it was available to Avema through the Freedom of Information Act, and was requested and obtained from the FDA following the change in ownership of the ANDA in March, 2011 as a result of Avema’s purchase of such asset from UPSCBC.

5. Attached hereto as Exhibit “A” is a letter from the FDA confirming its provision of records regarding ANDA 076460 which had been requested by Avema in April 2011.

6. Moreover, the Debtor and Mr. Patel misstate the applicable federal regulations as there is no requirement in 21 CFR 314.72 that “to fully consummate a sale of an ANDA, the seller must transfer to the buyer all of the complex documentation...”. Rather, 21 CFR 314.72 (a)(2)(iii) provides to the contrary in that “the new owner shall submit an application form signed by the new owner and a letter or other document containing the following:... a request for a copy of the application from FDA’s files. FDA will provide a copy of the application to the new owner under the fee schedule in Section 20.45 of FDA’s public information regulations.” As indicated above, PLD made such request and receive the relevant documents from the FDA.

7. Accordingly, there can be no issue as to Avema's compliance with the ownership requirements under the applicable portions of the CFR, and the Court must summarily reject the Debtor's attempts to argue to the contrary.

I hereby certify that the foregoing statements made by me are true. I am aware that if any such statements are willfully false I am subject to punishment.

Dated: September 30, 2011

By: /s/ Robert J. Anderson  
Robert J. Anderson

# **EXHIBIT A**



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Public Health Service**

*Food and Drug Administration  
Division of Freedom of Information  
12420 Parklawn Dr., Room 1050  
Rockville MD 20857*

May 27, 2011

Dana S. Toops  
Avena Pharma Solutions  
10400 NW 29<sup>th</sup> Terrace  
Miami, FL 33172

In Response Refer to File: 2011-2584

Dear Requestor,

This is in response to your request dated April 4, 2011, and received April 5, 2011, in which you requested the records for ANDA 076460, Ibuprofen Tablets USP, 200 mg.

The information you requested is enclosed. Generally, submissions appear as filed, in reverse chronological order. Also, there are two additional disks containing protocol data.

The enclosed records contain certain business or personal information which is disclosable only to your firm. Copies of these records would be disclosed to other requestors only after a thorough review and deletion of those portions which are not disclosable to the general public.

The following charges may be included in a monthly invoice:

*Reproduction: \$0.00 Search: \$276.00 Review: \$276.00 Other: \$3.00 (disks) TOTAL: \$555.00*

The above total may not reflect final charges for this request.

**PLEASE DO NOT SEND PAYMENT UNLESS YOU RECEIVE AN INVOICE FOR THE TOTAL MONTHLY FEE.**

**If there are any problems with this response, please notify us in writing of your specific problem(s). Please reference the above file number.**

This concludes the response for the Center for Drug Evaluation and Research. If I can be of further assistance to you, please do not hesitate to contact me.

Felicia Duffy  
CDR, USPHS  
Consumer Safety Officer  
Division of Information Disclosure Policy  
Office of Regulatory Policy  
Center for Drug Evaluation and Research  
Ph: 301-796-0148

Enclosure: CD-ROM disks (3)